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SCHEDULE B

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Federal Court of Appeal Cour d'appel fédérale

Docket: A-184-00
(T-415-95)

OTTAWA, ONTARIO, THIS 13TH DAY OF FEBRUARY 2001

CORAM: THE CHIEF JUSTICE
THE HONOURABLE MR. JUSTICE NOËL
THE HONOURABLE MR. JUSTICE EVANS

BETWEEN:

GLAXO GROUP LIMITED and GLAXO WELLCOME INC.

Appellants
(Applicants)

- and -

THE MINISTER OF NATIONAL HEALTH AND WELFARE and APOTEX INC.

Respondents
(Respondents)

JUDGMENT

The appeal is dismissed with costs to Apotex.

I HEREBY CERTIFY that the above document is a true copy of the original filed of record in the Registry of the Federal Court of Canada the 13th day of February A.D. 2001.
Dated this 15th day of February 2001.

J. Richard
C.J.

Federal Court of Appeal

Cour d'appel fédérale

Date: 20010402

Docket: A-233-00

Ottawa, Ontario, April 2, 2001

CORAM: RICHARD C.J.
NOËL J.A.
EVANS J.A.

GLAXO GROUP LIMITED
and GLAXO WELLCOME INC.

Appellants

and

THE MINISTER OF NATIONAL HEALTH AND WELFARE
and APOTEX INC.

Respondents

JUDGMENT

The appeal is dismissed with costs.

"J. Richard"
Chief Justice

I HEREBY CERTIFY that the above document is a true copy of the original filed of record in the Registry of the Federal Court of Canada the 2 day of April A.D. 20 01, dated this 5 day of April 20 01.

Federal Court of Appeal

Cour d'appel fédérale

Date: 20010402

Docket: A-233-00

Neutral citation: 2001 FCA 96

CORAM: **RICHARD C.J.**
NOËL J.A.
EVANS J.A.

BETWEEN:

GLAXO GROUP LIMITED
and GLAXO WELLCOME INC.

Appellants

and

THE MINISTER OF NATIONAL HEALTH AND WELFARE
and APOTEX INC.

Respondents

Heard at Ottawa, Ontario, on February 13, 2001.

Judgment delivered at Ottawa, Ontario, on April 2, 2001.

REASONS FOR JUDGMENT BY: RICHARD C.J.

CONCURRED IN BY: NOËL J.A.
EVANS J.A.

Federal Court of Appeal Cour d'appel fédérale

Date: 20010402

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CORAM: RICHARD C.J.
NOËL J.A.
EVANS J.A.

BETWEEN:

GLAXO GROUP LIMITED
and GLAXO WELLCOME INC.

Appellants

and

THE MINISTER OF NATIONAL HEALTH AND WELFARE
and APOTEX INC.

Respondents

REASONS FOR JUDGMENT

RICHARD C.J.

NATURE OF THE PROCEEDING

[1] This is an appeal from the Order of Mr. Justice O'Keefe, (2000), 6 C.P.R. (4th) 73, dismissing an application for prohibition brought by the appellants (Glaxo) pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the *Regulations*).

[2] The scheme of the *Regulations* has been dealt with by the application judge as well as in a number of decisions of this Court. It need not be repeated here.

POINTS IN ISSUE

[3] Glaxo raised three issues on appeal:

1. Is Apotex's allegation of non-infringement with respect to the '313 Patent and the '331 Patent justified;
2. Did the Court have jurisdiction to hear the application on its merits when Apotex failed to prove it filed a submission for a Notice of Compliance prior to (a) serving its Notice of Allegation and (b) the hearing of this matter below; and,
3. The adequacy of Apotex's Notice of Allegation.

ALLEGATION OF INFRINGEMENT

[4] Glaxo sought to prohibit the Minister of Health (Minister) from issuing to Apotex Inc. (Apotex) a Notice of Compliance for the medicine cefuroxime axetil in tablet form until after the expiry of Glaxo's Canadian Letters Patent Nos. 1,240,313 ('313 Patent) and 1,282,331 ('331 Patent).

[5] The appeal proceeded on the basis of the '313 Patent.

[6] The relevant claims of the '313 Patent are claims 15 and 18, which claim:

15. Cefuroxime axetil in highly pure, substantially amorphous form.

18. A pharmaceutical composition comprising cefuroxime axetil in highly pure, substantially amorphous form, in admixture with one or more pharmaceutical carriers or excipients.

[7] Thus, the requirements of the '313 Patent are that the cefuroxime axetil be in highly pure, substantially amorphous form and that this material be mixed with other materials to form the tablet composition.

[8] By a Notice of Allegation dated January 22, 1998, Apotex alleged that "no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by us of tablets containing the cefuroxime axetil."

[9] Following the issuance of a protective order, Apotex provided a further disclosure, setting out in complete detail the nature of its product.

[10] In support of its position, Apotex filed affidavits sworn by Dr. Bernard Sherman and by Dr. Eli Shefter.

[11] Dr. Sherman is Chairman of Apotex and has over 30 years experience in the area of pharmaceutical dosage forms. Dr. Sherman has designed every product ever made by Apotex and has supervised and directed the development of Apotex' cefuroxime axetil tablets.

[12] Dr. Shefter is an Adjunct Professor of pharmaceutical sciences at the University of Colorado and for over 30 years has been a consultant to various pharmaceutical and biotechnology companies with respect to the formulation, stability and quality control of pharmaceutical dosage form manufacture. Since 1985, Dr. Shefter has been a member of the United States Pharmacopoeia (USP) Committee of Revision.

[13] The affidavit evidence in support of Glaxo's position was provided by Dr. Ian K. Winterborn. Dr. Winterborn has a Ph.D. in physical chemistry and has worked exclusively for Glaxo either in the U.K. or in Canada since 1972.

[14] Mr. Justice O'Keefe correctly noted that the legal burden of proof rested on the applicant, Glaxo, to demonstrate to the Court on a balance of probabilities that the Apotex allegation is not justified.

[15] Mr. Justice O'Keefe construed the claims of the '313 patent and correctly concluded that, since the claims of the '313 patent claim highly pure cefuroxime axetil in substantially

amorphous form, the proper construction of the patent is that both of these properties must be present in a single substance.

[16] There can be no infringement of the '313 patent claims if both properties are not present in the cefuroxime axetil that is utilized.

[17] With regard to the allegation that the formulation would not be "substantially amorphous," Mr. Justice O'Keefe was not persuaded, on a balance of probabilities, that the Apotex formulation contained substantially amorphous cefuroxime axetil.

[18] He noted that it was a difficult determination, one that only rested on the burden of proof. Since Glaxo failed to meet its legal burden, Mr. Justice O'Keefe found that there could be no ruling that the Apotex allegation is not justified.

[19] Having found that the cefuroxime axetil used by Apotex was not, on the evidence before him, substantially amorphous, Mr. Justice O'Keefe properly concluded that the '313 patent was not infringed. While this was sufficient to end the inquiry, as Mr. Justice O'Keefe noted, he went on to review the evidence before him regarding purity.

[20] With respect to purity, i.e. the Glaxo claim that its cefuroxime axetil was "highly pure," Mr. Justice O'Keefe held that there was no highly pure cefuroxime axetil present in the Apotex formulation. In arriving at this conclusion, he preferred to rely upon the evidence of Dr. Shefter.

[21] As noted above, even if his finding that highly pure cefuroxime axetil is not present is incorrect, the claim of infringement by Glaxo would still not be established since the claims require that both properties i.e. " highly pure" and "substantially amorphous," be present together.

[22] Accordingly, he concluded that the Apotex formulation did not fall within the claims of the '313 Patent.

[23] With respect to the '331 Patent, Mr. Justice O'Keefe concluded that disintegration of the Apotex cefuroxime axetil tablets took place over a period of at least many minutes, and accordingly, the tablets did not fall within the claims of the '331 Patent.

[24] As stated by Hugessen J.A. in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.) at 319:

> As I understand the scheme of the regulations, it is the party moving under s. 6, ... which, as the initiator of the proceedings, has the carriage of the litigation and bears the initial burden of proof. That burden, as it seems to me, is a difficult one since it must be to disprove some or all of the allegations in the notice of allegation which, if left unchallenged, would allow the Minister to issue a notice of compliance.

[25] The judge's finding that he is "unable to find that there is in fact, substantially amorphous cefuroxime axetil in the Apotex precipitate" and "that there is not highly pure cefuroxime axetil present" are findings of fact, which were based on documentary evidence consisting of the affidavits of three expert witnesses and their cross-examinations.

[26] Appellate intervention with respect to findings of fact is warranted only where the lower court has made some palpable and overriding error. In *Stein v. "Kathy K" (The)*, [1976] 2 S.C.R. 802 at 808, Mr. Justice Ritchie for the Court wrote:

> These authorities are not to be taken as meaning that the findings of fact made at trial are immutable, but rather that they are not to be reversed unless it can be established that the learned trial judge made some palpable and overriding error which affected his assessment of the facts. While the Court of Appeal is seized with the duty of re-examining the evidence in order to be satisfied that no such error occurred, it is not, in my view, a part of its function to substitute its assessment of the balance of probability for the findings of the judge who presided at the trial.

[27] In *Toneguzzo-Norvell v. Burnaby Hospital*, [1994] 1 S.C.R. 114 at 121, the Supreme Court affirmed its earlier decision and stated:

> A Court of Appeal is clearly not entitled to interfere merely because it takes a different view of the evidence. The finding of facts and the drawing of evidentiary conclusions from facts is the province of the trial judge, not the Court of Appeal.

[28] As noted by Laskin J.A. in *Gottardo Properties (Dome) Inc. v. Toronto (City)* (1998), 162 D.L.R. (4th) 574 (Ont. C.A.) at 591:

> The absence of oral evidence does not however negate the desirability of a deferential standard of review. Deference is desirable for several reasons: to limit the number and length of appeals, to promote the autonomy and integrity of the trial or motion court proceedings on which substantial resources have been expended, to preserve the

> confidence of litigants in those proceedings, to recognize the competence of the trial judge or motion judge and to reduce needless duplication of judicial effort with no corresponding improvement in the quality of justice.

[29] Mr. Justice O'Keefe properly construed the claims, considered an ample body of evidence, weighed the evidence and concluded that he was not satisfied on the balance of probabilities that the appellants had discharged the burden of proof to establish that the allegation of non infringement is not justified. In so finding, Mr. Justice O'Keefe did not make any palpable or overriding error that would warrant allowing the appeal on this basis.

NON-COMPLIANCE WITH AMENDED REGULATIONS

[30] Counsel for the appellant also alleged that an Amended New Drug Submission (ANDS) must be filed before service of the Notice of Allegation or at least prior to the hearing of the application. The basis for Glaxo's argument is the amendment to clause 5(3)(c)(i) of the *Regulations* made March 12, 1998, as well as the effect and interpretation of the transitional provisions contained in subsection 9(1).

[31] Mr. Justice O'Keefe did not find it necessary to determine whether the amended regulations require that documents be filed in a particular manner or that they were not complied with in the circumstances, as Glaxo had failed to lead any evidence that would support the facts necessary to support its position on this issue.

[32] In other words, Glaxo failed to establish whether and when Apotex filed its ANDS, despite the fact that subsection 6(7) of the *Regulations* permits Glaxo to seek disclosure of such information.

[33] Before us, Glaxo relied on portions of the record which it claimed were highly circumstantial in an attempt to show that Apotex had inferentially admitted its failure to file an ANDS as allegedly required by the *Regulations*. In these circumstances, and given that, unlike Glaxo, Apotex has direct knowledge of when it filed its ANDS, the legal burden of proving the date of the filing was borne by Apotex.

[34] This argument fails for two reasons.

[35] First, contrary to Glaxo's suggestion, there is no clear evidence before the Court that Apotex had not complied with the *Regulations*, as amended, or the transitional provisions. Neither party filed any evidence and Glaxo's reliance on answers to questions on cross-examination cannot be determinative, but at best amounts to speculation. This Court cannot draw any conclusions from the evidence concerning the date that Apotex filed the ANDS.

[36] Secondly, there is no doubt that the burden of proof is on the party who asserts a particular fact. If Glaxo was unable to prove the necessary facts, it needed to demonstrate that the required information was not adduced in evidence by Apotex and that Glaxo had no other means

available of accessing it in order to shift the burden of proof: see *Eli Lilly and Co. v. Nu-Pharm Inc.* (1996), 69 C.P.R. (3d) 1 (F.C.A.) at 20.

[37] However, Glaxo had other means available with which to compel the necessary information. Subsection 6(7) of the *Regulations* provides a mechanism by which a first person such as Glaxo may compel production of any relevant portions of an ANDS. It reads as follows:

(7) On the motion of a first person, the court may, at any time during a proceeding,	(7) Sur requête de la première personne, le tribunal peut, au cours de l'instance :
(a) order a second person to produce any portion of the submission for a notice of compliance filed by the second person relevant to the disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made; and	(a) ordonner à la seconde personne de produire les extraits pertinents de la demande d'avis de conformité qu'elle a déposée et lui enjoindre de produire sans délai tout changement apporté à ces extraits au cours de l'instance;
(b) order the Minister to verify that any portion produced corresponds fully to the information in the submission.	(b) enjoindre au ministre de vérifier que les extraits produits correspondent fidèlement aux renseignements figurant dans la demande d'avis de conformité.

[38] This Court has recently held that an applicant for production pursuant to subsection 6(7) does not bear a heavy burden with respect to obtaining production: *Novartis Inc. v. Abbott Laboratories Inc.*, [2000] F.C.J. No. 941 (F.C.A.).

[39] It was at all times open to Glaxo to pursue this remedy and to secure access to the information sought. Glaxo simply failed to do so, and now seeks to avoid the consequences of

this failure. In circumstances where Glaxo had a clear opportunity to obtain this information and failed to do so for no apparent reason, it cannot be said that there is any burden or obligation whatsoever on Apotex to introduce evidence in support of an issue raised by Glaxo.

INSUFFICIENCY OF THE NOTICE OF ALLEGATION

[40] Glaxo further alleges that the legal and factual basis provided by Apotex for its allegation was insufficient or deficient.

[41] As noted earlier, following the issuance of a protective order, Apotex provided a further disclosure, setting out in complete detail the nature of its product.

[42] After considering Glaxo's arguments, Mr. Justice O'Keefe held that the Notice of Allegation and Further Disclosure provided a sufficient legal and factual basis for the allegations made. This is consistent with the finding of this Court in *Bayer AG v. Canada* (1993), 51 C.P.R. (3d) 329 (F.C.A.) that while bald assertions of non-infringement are insufficient, it is permissible to withhold certain information regarding allegations until a confidentiality order has been issued.

[43] The facts relied upon by Apotex were disclosed in its Notice of Allegation and Further Disclosure.

[44] Even if, as the appellant suggests, the application judge erred in finding that the purity of the Apotex formulation was not properly raised and in allowing Apotex to lead evidence on this issue, the outcome is not affected since the application judge found that the cefuroxime axetil was not substantially amorphous. Thus, the '313 patent is not infringed.

DISPOSITION

[45] The appeal will be dismissed with costs.

"J. Richard"
Chief Justice

"I agree
Marc Noël J.A."

"I agree
John M. Evans J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-233-00
STYLE OF CAUSE:	Glaxo Group Limited and Glaxo Wellcome Inc. -and- The Minister of National Health and Welfare and Apotex Inc.
PLACE OF HEARING:	Ottawa
DATE OF HEARING:	February 14, 2001
REASONS FOR JUDGMENT BY	Richard, C.J.
CONCURRED IN BY:	Noël, J.A. and Evans, J.A.
DATED:	April 2, 2001

APPEARANCES:

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Mr. Harry Radomski Ms. Julie M. Perrin	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

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Morris Rosenberg, Ottawa (for Minister of National Health and Welfare)	FOR THE RESPONDENT